

## **Tips for Inert Ingredients**

### ***Draft 10/31/06***

#### **What is an “inert ingredient”?**

The majority of pesticide products contain chemicals in addition to the active ingredient. These chemicals are called “inert ingredients” under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA defines an inert ingredient as one that is intentionally added to a pesticide formulation and is not pesticidally active, such as solvents, carriers, aerosol propellants, fragrances, and dyes. It is important to note that the term “inert” does not imply non-toxicity. Impurities are not included in the definition of inert ingredient. Every inert ingredient must be approved for use by EPA before they can be used in pesticide products, and tolerances or exemptions from the requirement of a tolerance are required for inert ingredients used in pesticide products applied to food.

This document provides helpful tips for finding approved inert ingredients, filling out the information about inert ingredients in Confidential Statements of Formula (CSF), and how to contact EPA’s Inert Ingredient Assessment Branch with questions about inert ingredients.

#### **How can I find inert ingredients that are approved for use in pesticide products?**

Pesticide registrants who want to use an inert ingredient in their pesticide product must first ensure that it has been approved by EPA. As part of the Agency’s review of an application for the registration of a pesticide product, the Agency will review the product’s composition information and the CSF to verify that all of the inert ingredients proposed for use in the pesticide formulation have been approved by the Agency. It is strongly recommended that registrants confirm the approval status of all components of their new product prior to submitting a registration application.

It is important to determine the approved use of the inert ingredient before including it in your products because many limitations exist. Inert ingredients can be approved for use in pesticide products applied either to:

1. Non-food sites **only**, such as ornamental plants, lawns, highway right-of-ways, etc., **OR**
2. Food sites (food and feed crops, raw agricultural commodities, or livestock used for food) **and** non-food sites. It is important to note that use on food requires a tolerance/exemption from the requirement of a tolerance (e.g. tolerance exemption) and the use is usually limited in some fashion.

The following discusses 1) how to identify the approved uses of inert ingredients, and 2) for food-uses, the tolerance/tolerance exemptions that are required and the importance of observing any use limitations.

#### **Non-Food Use Inert Ingredients.**

All approved inert ingredients can be included in pesticide products that are applied to **non-food** sites. Inert ingredients approved for non-food uses are listed on the Inert Ingredient website at <http://www.epa.gov/opprd001/inerts/lists.html>. The list is available in two formats – “CAS Number” or

“chemical name”. The links to the two formats are found in the middle of the webpage just below the box with the spider’s web in the left-hand corner.

Curious about the meaning of the spider’s web? It is a symbol EPA uses to alert readers that a webpage contains out-of-date information. The updated list of inert ingredients should be available on this website in early 2007. The updated list will include existing and newly approved inert ingredients, and all inert ingredients will be identified with their CAS numbers. Please note that only these CAS numbers are approved for use in non-food pesticide products. Please contact IIAB with questions (see below).

### **Food Use Inert Ingredients.**

Some inert ingredients are approved for use in pesticide products applied to **food** sites (food and feed crops, raw agricultural commodities, or livestock used for food). The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that all inert ingredients used in pesticide products applied to food sites must have a tolerance/tolerance exemption in the Code of Federal Regulations (CFR) under 40 CFR part 180.

#### ***CFR sections and use limitations***

Tolerances/tolerance exemptions often contain limitations on how the inert ingredient can be used in the food-use pesticide products. It is very important to pay attention to the use limitations when selecting an inert because products will not be approved if their uses do not comply with the limitations in the tolerance/tolerance exemption. 40 CFR part 180 organizes inert ingredients into sections by general limitations, as follows:

- § 180.910 permits use when applied to growing crops or to raw agricultural commodities after harvest.
- § 180.920 permits use when applied to growing crops only.
- § 180.930 permits use when applied to animals.
- § 180.940 permits use in antimicrobial formulations applied as food-contact surface sanitizing solutions.
- § 180.950 permits unlimited use of minimal risk active and inert ingredients.
- § 180.960 permits unlimited use of chemicals that meet the definition of a polymer and the criteria specified for defining a low-risk polymer in 40 CFR 723.250.

Please note that in addition to the general limitations of sections §§ 180.910, 920, and 930, each tolerance exemption may have chemical-specific limitations that must be complied with. For example, the tolerance exemption in § 180.920 for 3,6-Dimethyl-4-octyn-3,6-diol permits use on growing crops but limits its use to applications to “soil prior to planting or to plants before edible parts form.”

40 CFR part 180 also contains a number of sections that are tolerances/exemptions for specific inert ingredients, and that their use is usually significantly limited. An example is § 180.1065, which is a tolerance exemption for 2-Amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5- $\alpha$ )pyrimidin-5-one when it is used as an emetic at not more than 0.3 percent in formulations of paraquat dichloride.

#### ***How to use the E-CFR***

EPA recommends that you use the on-line CFR – called the e-CFR – because it is updated daily. The changes made to tolerance exemptions as a result of FQPA tolerance reassessment occurred after the

most recent printing of the CFR hard-copy book. Therefore, the e-CFR is the source for finding the most up-to-date listing of inert ingredients with tolerances/tolerance exemptions. Please be aware that some of the inert ingredients found listed on the Inert Ingredient website (discussed above) also have tolerance/tolerance exemptions and can be used on food. Unfortunately, the website does not specify which ones can be used on food and which are solely for use in non-food pesticide products.

You can access the 40 CFR part 180 on the e-CFR at the following website address (the e-CFR is a beta website so the address is quite long):

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=6541215c6327d2d3ef7ac3ddfb3352da&rgn=div5&view=text&node=40:23.0.1.1.27&idno=40#40:23.0.1.1.27.4.27.3>

If the above link doesn't work, follow these instructions for finding 40 CFR part 180 in the e-CFR:

- Go to <http://www.gpoaccess.gov/cfr/index.html>
- On the left side under "Related Resources", click on "e-CFR".
- Under "Browse", select "Title 40: Protection of Environment" and click "Go".
- Under the column "Browse Parts", click on "150-189".
- Under the column "Part", click on "180".

Once in § 180, scroll down and click on the section you want. Once in a section, please be aware that you may need to scroll down to find the exemptions. In §§ 180.910, 920, and 930, click on "Link to an amendment..." to find the recent changes to tolerance exemptions.

Some tolerances/tolerance exemptions are broadly written and describe more than one chemical. In the future, the CFR entries for each tolerance/tolerance exemption will include the approved CAS numbers. Until then, if you are unsure if your chemical is part of a tolerance exemption, please contact the Inert Ingredient Assessment Branch (see below).

### **What do I put on my Confidential Statement of Formula (CSF) for Inert Ingredients?**

It is important that you clearly identify all inert ingredients on the CSF. For each inert ingredient, provide the chemical names and CAS numbers. For food use products, also identify the tolerances/tolerance exemptions that are associated with each inert. For more information on filling out the CSF, please see "Tips to Registrants/Applicants to Avoid Common Errors in Product Chemistry Submissions for Registration and Reregistration of Pesticide Chemicals", which is found in the Blue Book.

If you use a proprietary blend (often called a 'mixture') of inert ingredients in your formulations, please identify the mixture's trade name. It is important to note that the mixture must already be approved by EPA. If the trade name is not on file with EPA or if there are non-approved inert ingredients in the blend, your product will be rejected. Check first with your supplier to ensure that EPA has approved the mixture and that the components of the blend have not changed since it was approved by EPA.

Be aware that EPA will not approve product formulations that contain unapproved inert ingredients. If a new inert ingredient tolerance/tolerance exemption is needed, a petition (with data) must be submitted for new tolerance exemptions. If approval of a new non-food use inert ingredient is needed, a letter

requesting an approval must be submitted along with supporting information. The Blue Book provides information on both of these approval processes. Contact IIAB if you have questions.

### **How do I contact the IIAB?**

For technical questions, such as questions about chemical nomenclatures and chemicals included in inert ingredient tolerance exemptions, please contact:

- Pauline Wagner, IIAB Chief, 703-308-6164, [wagner.pauline@epa.gov](mailto:wagner.pauline@epa.gov)
- Kerry Leifer, Team Leader, 703-308-8811, [leifer.kerry@epa.gov](mailto:leifer.kerry@epa.gov)

For general information on inert ingredients, the approval status of a particular chemical, and the final revocation rules, please contact:

- Karen Angulo, Team Leader, 703-306-0404, [angulo.karen@epa.gov](mailto:angulo.karen@epa.gov)

The Agency recommends for security purposes that parties not fax or e-mail any document or correspondence containing CBI.

### **Mailing documents and correspondence.**

Hardcopies of letters and documents can be mailed to the IIAB at the addresses below:

#### **Mail**

Document Processing Desk (Inert Ingredient Assessment Branch - IIAB)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave. NW  
Washington, D.C. 20460

#### **Courier Address:**

Inert Ingredient Assessment Branch (IIAB)  
Office of Pesticide Programs  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202